

## **WHAT IS CLAIMED IS:**

1. A film product formed by the steps of:
  - (a) combining a polymer and a polar solvent to form a material with a non-self-aggregating uniform heterogeneity;
  - (b) forming said material into a film; and
  - (c) drying said film in a controlled manner to maintain said non-self-aggregating uniform heterogeneity.
2. The film product of claim 1, wherein said film includes a top side and a bottom side and said drying includes drying said bottom side first.
3. The film product of claim 1, wherein said drying includes applying heat to said bottom side.
4. The film product of claim 1, wherein said polar solvent is a combination of water and a polar organic solvent.
5. The film product of claim 1, wherein said polar solvent is water.
6. The film product of claim 1 further comprising an active component.
7. The film product of claim 1, wherein said polar solvent added in step (a) has a weight percent of at least about 30%.
8. The film product of claim 1, wherein said drying of said film reduces the weight percent of said polar solvent to about 10% or less.
9. The film product of claim 1, wherein said drying of said film reduces the weight percent of said polar solvent to about 8% or less.

10. The film product of claim 1, wherein said drying of said film reduces the weight percent of said polar solvent to about 6% or less.

11. The film product of claim 6, wherein said active component is a member selected from the group consisting of medicaments, flavors, fragrances, enzymes, preservatives, sweetening agents, colorants, spices, vitamins, and combinations thereof.

12. The film product of claim 1, wherein said drying occurs within about 10 minutes or fewer.

13. The film product of claim 1, wherein said polymer is a member selected from the group consisting of water soluble polymers, water insoluble polymers, and combinations thereof.

14. The film product of claim 1, wherein said polymer is a cellulose derivative.

15. The film product of claim 13, wherein said water soluble polymer is a member selected from the group consisting of hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, polyvinylpyrrolidone, carboxymethyl cellulose, polyvinyl alcohol, sodium aginate, polyethylene glycol, xanthan gum, tragacanth gum, guar gum, acacia gum, arabic gum, polyacrylic acid, methylmethacrylate copolymer, carboxyvinyl copolymers, starch and combinations thereof.

16. The film product of claim 13, wherein said water insoluble polymer is a member selected from the group consisting of ethyl cellulose, hydroxypropyl ethyl cellulose, cellulose acetate phthalate, hydroxypropyl methyl cellulose phthalate, and combinations thereof.

17. The film product of claim 1, wherein said film product has a thickness of greater than about 0.1 mils.

18. The film product of claim 1, wherein said film product has a thickness of about 10 mils or fewer.

19. The film product of claim 1, wherein said film product has a substantially uniform thickness.
20. The film product of claim 6, wherein said film product is divided into dosage forms of substantially equal dimensions.
21. The film product of claim 20, wherein each of said dosage forms contains a substantially equal amount of said active.
22. The film product of claim 20, wherein said dosage forms contain an amount of said active that varies about 10% or less among said dosage forms.
23. A process for making a film having a substantially uniform distribution of components comprising:
- (a) combining a polymer component and polar solvent to form a matrix with a uniform distribution of said components;
  - (b) forming a film from said matrix;
  - (c) providing a surface having top and bottom sides;
  - (d) feeding said film onto said top side of said surface; and
  - (e) drying said film by applying heat to said bottom side of said surface.
24. The process of claim 23, further comprising the step of adding an active component to said matrix of step (a).
25. The process of claim 23, wherein said film is ingestible.
26. The process of claim 23, wherein said drying step maintains a non-self-aggregating uniform heterogeneity of said components throughout said film.
27. The process of claim 23, wherein said film is flexible when dried.

28. The process of claim 23, wherein said film is self-supporting.
29. The process of claim 24, wherein uniform distribution determines the amount of active material component per area.
30. The process of claim 24, wherein a specific amount of the active material component may be obtained from said film by cutting said film to a predetermined size.
31. The process of claim 23, wherein said drying of said film occurs within about 10 minutes or fewer.
32. A method of orally administering an active comprising the steps of:
- (a) preparing a film by the steps of:
    - (i) combining a polymer, an active component, and water to form a material with a non-self-aggregating uniform heterogeneity;
    - (ii) forming said material into a film; and
    - (iii) drying said film in a controlled manner to maintain said non-self-aggregating uniform heterogeneity; and
  - (b) introducing said film to the oral cavity of a mammal.
33. A method of introducing an active component to liquid comprising the steps of:
- (a) preparing a film by the steps of:
    - (i) combining a polymer, an active component, and a polar solvent to form a material with a non-self-aggregating uniform heterogeneity;
    - (ii) forming said material into a film; and
    - (iii) drying said film in a controlled manner to maintain said non-self-aggregating uniform heterogeneity; and
  - (b) placing said film into a liquid; and
  - (c) allowing said film to dissolve.

34. The method of claim 33, wherein said active ingredient is a flavoring.
35. The method of claim 34, wherein said flavoring is selected from the group consisting of hot and cold beverage flavorings and soup flavoring.
36. The method of claim 33, wherein said liquid is ingestible.
37. A dosage form for the administration of an active comprising:
- (a) a first layer comprising a film formed by the steps of:
    - (i) combining a polymer, an active component, and a polar solvent to form a material with a non-self-aggregating uniform heterogeneity;
    - (ii) forming said material into a film; and
    - (iii) drying said film in a controlled manner to maintain said non-self-aggregating uniform heterogeneity; and
  - (b) a substantially non-water soluble second layer.
38. The dosage form of claim 37, wherein said first layer is removable from said second layer.
39. The dosage form of claim 37, wherein said film may be applied to the tongue of a mammal.
40. The dosage form of claim 37, wherein said film has a shape comprising first and second opposing bases wherein first base is longer than said second base.
41. The dosage form of claim 37, wherein said film has a shape selected from the group consisting of trapezoid and triangle.
42. The dosage form of claim 37, wherein said film adheres to an oral cavity.

43. The dosage form of claim 37, wherein said film includes an adhesive to adhere said film to an oral cavity.

44. A method of preparing a dosage form for the administration of an active comprising the steps of:

- a. combining a polymer, an active component, and a polar solvent to form a material with a non-self-aggregating uniform heterogeneity;
- b. forming said material into a film;
- c. applying said film to a substantially non-water soluble support; and
- d. drying said film in a controlled manner to maintain said non-self-aggregating uniform heterogeneity.

45. A method of administering an active comprising the steps of:

- (a) preparing dosage form by the steps of:
  - (i) combining a polymer, an active component, and a polar solvent to form a material with a non-self-aggregating uniform heterogeneity;
  - (ii) forming said material into a film;
  - (iii) applying said film to a substantially non-water soluble support; and
  - (iv) drying said film in a controlled manner to maintain said non-self-aggregating uniform heterogeneity;
- (b) removing said film from said support; and
- (c) applying said film to the oral cavity of a mammal.

46. The method of claim 45, wherein said active is released as said film dissolves.

47. A film product formed by the steps of:

- (a) combining a water soluble polymer and water to form a material with a non-self-aggregating uniform heterogeneity;
- (b) forming said material into a film; and
- (c) drying said film in a controlled manner to maintain said non-self-aggregating uniform heterogeneity.

48. A film product formed by the steps of:

- (a) combining a polymer and a polar solvent to form a material with a non-self-aggregating uniform heterogeneity, said polymer selected to provide a viscosity sufficient to maintain said non-self aggregating heterogeneity;
- (b) forming said material into a film; and
- (c) drying said film.

49. A film product formed by the steps of:

- (a) combining a polymer and a polar solvent to form a material with a non-self-aggregating uniform heterogeneity;
- (b) forming said material into a film by reverse roll coating; and
- (c) drying said film in a controlled manner to maintain said non-self-aggregating uniform heterogeneity.

50. A film product formed by the steps of:

- (a) combining a polymer and a polar solvent to form a material with a non-self-aggregating uniform heterogeneity, said polymer selected to provide a viscosity sufficient to maintain said non-self aggregating heterogeneity;
- (b) forming said material into a film by reverse roll coating; and
- (c) drying said film in a controlled manner to maintain said non-self-aggregating uniform heterogeneity.

51. A process for making a film having a substantially uniform distribution of components comprising:

- (a) combining a polymer component, and polar solvent to form a matrix with a uniform distribution of said components, said polymer selected to provide a viscosity sufficient to maintain said uniform distribution;
- (b) forming a film from said matrix;
- (c) providing a surface having top and bottom sides;
- (d) feeding said film onto said top side of said surface; and

- (e) drying said film by applying heat to said bottom side of said surface.

52. A process for making a film having a substantially uniform distribution of components comprising:

- (a) combining a polymer component, and polar solvent to form a matrix with a uniform distribution of said components;
- (b) forming a film from said matrix by reverse roll coating;
- (c) providing a surface having top and bottom sides;
- (d) feeding said film onto said top side of said surface; and
- (e) drying said film by applying heat to said bottom side of said surface.

53. A process for making a film having a substantially uniform distribution of components comprising:

- (a) combining a polymer component, and polar solvent to form a matrix with a uniform distribution of said components, said polymer selected to provide a viscosity sufficient to maintain said uniform distribution;
- (b) forming a film from said matrix by reverse roll coating;
- (c) providing a surface having top and bottom sides;
- (d) feeding said film onto said top side of said surface; and
- (e) drying said film by applying heat to said bottom side of said surface.

54. A process for making a film having a substantially uniform distribution of components comprising:

- (a) combining a polymer component and polar solvent to form a matrix with a uniform distribution of said components;
- (b) forming a film from said matrix; and
- (c) drying said film by feeding said film onto a surface having top and bottom sides; said bottom side being in substantially uniform contact with a water bath at a temperature sufficient to dry said film.

55. The process of claim 54, wherein said water bath is temperature controlled.



56. A pharmaceutical and/or cosmetic dosage form comprising a film having a uniformly dispersed composition comprising a polymer, a pharmaceutical and/or cosmetic active and a solvent, said film being formed by depositing a wet film of said composition onto a substrate surface and controllably drying the wet film from the side contacting the substrate to prevent self-aggregation and achieve compositional uniformity.
57. A pharmaceutical and/or cosmetic dosage form comprising a polymeric film having no more than a 10% variance of a pharmaceutical and/or cosmetic active per unit area.
58. A pharmaceutical composition in the form of a film for enteral or topical administration, comprising a composition having a uniformly distributed combination of a polymer, a polar solvent, and a pharmaceutical active, said composition in its dried film form maintaining the uniform distribution of components through the application of controlled bottom drying of the film.
59. The pharmaceutical composition of claim 58 in unit dosage form sealed in a pouch.
60. A pharmaceutical dispenser comprising individual unit dosage forms of the pharmaceutical composition of claim 58.
61. The dispenser of claim 60 wherein said individual unit dosage forms are in a roll or stacked in a dispenser.